PATENT
Customer No. 22,852
Attorney Docket No. 04853.0086

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
OGATA et al.	Group Art Unit: 1646
Application No.: 10/019,571	Examiner: Ruixiang Li
PCT Filing Date: July 3, 2000	
§ 371 Date: December 31, 2001	
For: THERAPEUTIC AGENT FOR DISEASES CAUSED BY PTH OR PTHrP	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement dated September 15, 2003, the Examiner required election of a single species from the following groups:

Species (i) Active ingredients: an agonist, an antagonist, a substance that binds to a ligand of a PTH receptor/PTHrP receptor to promote binding between the ligand and the receptor, and a substance that binds to a ligand of a PTH receptor/PTHrP receptor to inhibit binding between the ligand and the receptor.

Species (ii) Diseases mediated by PTH or PTHrP: a syndrome associated with malignancy as listed in claims 5 and 23, secondary hyperparathyroidism, primary hyperparathyroidism, a central nervous system disease as listed

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in claim 8, a disease mediated by PTH - or PTHrP-cytokine cascade as listed in claim 11.

Species (iii) Cytokines listed in claim 10.

Applicants provisionally elect, with traverse, to prosecute a substance that binds to a ligand of a PTH receptor/PTHrP receptor to inhibit binding between the ligand and the receptor, from Species (i); a disease mediated by PTH - or PTHrP-cytokine cascade as listed in claim 11, from Species (ii); and IL-6 listed in claim 10, from Species (iii).

In making the restriction requirement, the Examiner is requiring Applicants "to elect a single species from (i), (ii), and (iii) to which the claims shall be restricted if no generic claim is finally held to be allowable." Office Action at page 2. This application was filed pursuant to 35 U.S.C. § 371. Therefore, restriction under 35 U.S.C. § 121 does not apply to this application. Instead, this application should be measured against the PCT unity of invention regulations. The PCT unity of invention regulations do not contain a provision for the election of species.

The Examiner is improperly combining PCT law of unity of invention with U.S. Restriction Requirement law under 35 U.S.C. § 121. These two distinct bodies of practice cannot be combined. In this national stage application based on a PCT application, the Examiner must use the PCT law of unity of invention and only the PCT law of unity of invention. The requirement of electing a patentably distinct species is a construct of the U.S. Restriction Requirement law, and should not be made in this case. *Compare* MPEP Chapter 800 with Annex B of the PCT Administrative Instructions at the back of the MPEP. Thus, while Applicants have designated patentably distinct species, the law requires the Examiner to examine all of the claims together.

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Additionally, not all the PTH- or PTH-rP-related diseases, listed by the Examiner in species (ii), are necessarily mediated by a PTH- or PTHrP-cytokine cascade. Therefore, it is not appropriate to require that a species of cytokine from Species (iii) be elected. Thus, Applicants request that the Examiner withdraw the requirements to elect species.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: February 17, 2004

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